Pharmacovigilance Working Group Meeting Minutes

Thursday, 23rd May, 2024 | 14:00 CET. Online, via Zoom

Participants:
Rajinder Suri (RS), Beatriz Lucchesi (BL), Patricia Mouta (PM), Devang Patel (DP), Renata Pedro (RP), Reza Bosman (RB), Shuyan Zuo (SZ), Comfort Ogar (CO), Katharina Harmann (KH), Sonia Villaseñor (SV).
Meeting started at 14:10 CET and adjourned at 15:09 CET.

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1. Welcome

SV welcomed the participants and introduced CO from the U.S. Pharmacopeial Convention (USP), who will be supporting the Pharmacovigilance Working Group. The participants then took turns briefly introducing themselves and their pharmacovigilance experience.

2. Update on the AVSS (Active Vaccine Surveillance System) project

KH noted that one-on-one interviews have been conducted, together with Marc Ceuppens, with 7 DCVMN member companies that submitted protocols. The feedback given was very useful. A presentation for the closeout webinar planned for next week is being prepared to share feedback, CB from SII will also be presenting their experience in actually running an AVSS project. A publication summarizing the learnings from the project will be ready for submission by the end of June.

3. Analysis of PV maturity survey results

PM presented the results of a survey on the pharmacovigilance maturity of DCVMN member companies. 34 companies participated in the survey and results were analyzed anonymously. The survey found that most companies are at a developing or functional level of maturity for almost all the items, with adverse event management and aggregate reporting being the most mature areas. Challenges were identified in areas like safety governance, risk management, and signal management. Some examples given refer to manual processes, limited AI implementation, late start and staff experience, and risk control management. Some companies do not already compile a DSUR. There is the need of more visibility of the PV activities. It would be interesting to compare these results with the survey conducted in 2019. KH mentioned that she has seen in general a great advance in the maturity of the PV system, compared to 5 years ago. It is not surprising that DCVMN companies are still struggling, but are on the right track, and the experience from high income countries can be transferred. So we're moving, slowly, but surely.

- The group shared their insights in the same sense of having learnt very much through this project despite the challenges faced. RS suggested to also look for mitigation strategies to those three challenges and a small group can volunteer to come up with a plan of solutions to these challenges and present it for the next time. PM will share the slide deck with the participants; BL and DP offered to contribute to this analysis. KH can support by bringing some experiences on how to make sure to comply with the regulation.

PM also presented a proposal for process alignment between PV, clinical, and regulatory teams. The proposal included first a mapping of the activities that have interfaces between PV and Regulatory and between PV and Clinical development. PM mentioned there is a list of several SOPs for PV. The rationale was to think about the main processes interfacing with each of these areas and think what kind of SOPs would be needed to elaborate or to reveal first to improve the collaboration between the departments.
It is important to align key processes between pharmacovigilance, clinical development, and regulatory affairs, such as PSUR, DSUR and RMP preparation, label updates, safety planning in clinical trials, and safety monitoring. The group agreed this to be an important area to address, and volunteers, including BL, DP and CO offered to work with Patricia on developing standard operating procedures and addressing the identified gaps.
KH also proposed to start with a full understanding of the interrelated processes, from start to end, what are the documents required at each stage and where and when is safety management involved, and then identify what is needed, RS emphasized on identifying where the gaps are and addressing them. KH suggested to have a webinar on the topic. KH had already shard a slide set on safety in clinical development. It would be interesting for people to look at them. These processes are developing continuously.

RS congratulated the team for their advances and expressed his contentment on how the PV group is evolving thanks to the impact of KH. The next steps will be discussed further in the next meeting.

Notes taken by SVB 23 May 2024

Patricia Mouta
Chair